

3185

Dr. NAME, Ph.D.

Re: Prenotice Communication 3185

Dear Dr. NAME:

This letter responds to your letter of 16 November 2001 sent to Dave Schutz of my staff, and which included as attachments letters sent on November 8, 1996 to Mary Cushmac, on Jan. 31, 1997 to Mary Cushmac, on June 5 1998 to me, and on June 21, 2000 to Dave Schutz. The 16 November 2001 letter informs the Agency that the maker of the materials which were the subjects of the earlier letters is now QQ Company. The November, 1996 letter describes products [COMPANY OWNERSHIP DISCUSSED] The earlier letters both request an official Environmental Protection Agency (EPA, Agency) response on your company's determination that certain salt substances found in your firm's products can be exempt from Inventory listing otherwise required under section 5 of the Toxic Substances Control Act (TSCA) because they meet the criteria for exemption at 40 Code of Federal Regulations (CFR) 720.30(h)(7). If, in the alternative, the Agency found that these materials could not be excluded under (h)(7), you requested that the Agency determine that it was reasonable to believe that these substances were excluded prior to issuance of Agency guidance on the (h)(7) exclusion in the June 29, 1994 letter from Joseph Carra, then Deputy Director of OPPT.

As you noted, the 1994 letter from Joseph Carra provides guidance on the exclusion found at 40 CFR §720.30(h)(7). This letter states that an excluded substance is one that meets the following three criteria:

- 1) The substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) and which functions as intended, or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic;
- 2) The substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) The substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

In general, if a substance on which you requested guidance must be in salt form for your firm or its customers to use it at all, it is reportable. This letter will discuss the substances you presented in your letters as a group. The discussions of individual products provided in your letters did not raise issues which required separate discussion.

You describe situations in which the predominant components of your formulations are XXXXs with carboxy or hydroxy functional groups. The XXXXXs function as binders or coating components. These materials themselves give the formulations a low pH, and as a result they would not disperse in the products if the pH were not raised by the addition of some sort of

base. Upon addition of the base, a salt is expected to form between it and the XXXXX, and the salt disperses adequately at the raised pH. You stated your position that in these cases the reaction between the bases and the XXXXs does not result in substances which function to provide a primary property of the product.

Based on the facts as you described them, however, the Agency disagrees with your position: if the materials must disperse to be useful in their intended function, and the carboxy and hydroxy materials will not disperse at the low pH which they themselves cause, the salt which is present at the increased pH at which dispersal can occur has the primary property of functioning as a binder or coating component. Since the salt must be made because the non-salt XXXX does not disperse adequately, it does not meet Criterion 2 of the exemption.

If the carboxy and hydroxy forms of the XXXXs had adequate dispersing properties, and if the salt formation were simply incidental to the addition of a substance serving one of the purposes identified in criterion 1, above, then the (h)(7) exemption would be applicable. The other situation in which the (h)(7) exclusion could apply to the salt would be if you could show that the salt did not provide the binding/coating properties, but the properties were provided by the small equilibrium fraction of the XXXX material which came out of salt form at the raised pH. Absent data showing this to be the case, though, this material must be the subject of a premanufacture notice. Thus the materials do not satisfy the criteria identified in the Carra letter of 29 June 1994.

EPA does, however, agree that it was possible, in the matter of the substances which you have identified in your letters, for [COMPANY OWNERSHIP DISCUSSED] and QQ Company to have believed in good faith that they were acting within the scope and intent of the exclusion found at 40 CFR §720.30(h)(7), and that PMNs filed for this material can be filed under the clarification policy based on the Carra letter. Further, if there are other substances which you believe to be similarly appropriate for consideration under this policy, the Agency invites you to describe them to us for a determination.

I hope this letter adequately responds to your request. If you have remaining questions, feel free to contact Mr. Schutz of my staff at 202-564-9262.

Sincerely,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch
Chemical Control Division (7405)

cc:CCC

3345

Mr. YYY

Re: PC 3345

Dear Mr. YYY:

This letter is a further clarification of our previous letter to you dated January 21, 1998 regarding the appropriateness of exclusion under the Toxic Substances Control Act (TSCA) from the requirement for premanufacture notification (PMN) under Code of Federal Regulations (CFR) §720.30(h)(7) for a family of treated [SUBJECT MATERIAL] products. The identity of your client and the nature of the chemical substances and reactions to which your inquiry is addressed were disclosed to us in your letter of December 11, 1997. You have stated that in the process of producing water dispersible inks, you treat [SUBJECT MATERIAL] to make Salt A. Salt A then undergoes ionic exchange to form Acid B, which subsequently undergoes a further ionic exchange to make Salt C. You note that these reactions that convert Salt A to Acid B and Acid B to Salt C are ionic exchanges, and that the purpose of the manipulations is to modify the physicochemical characteristics (water fastness is one example of a physicochemical characteristic that may be modified) of the substance for which you have commercial intent. You further state that it is not your intention to form, for distribution in commerce as chemical substances per se, the salts/acids of [SUBJECT MATERIAL] which result from these reactions, that they have no purpose separate from the colorant of which they are a part, and that the substance functions as a colorant regardless of whether it is in salt/acid form.

The Environmental Protection Agency (EPA, Agency) has issued guidance, in the form of a June 29, 1994 letter from Joseph Carra, Deputy Director of the Office of Pollution Prevention and Toxics (OPPT) on the exclusion found at 40 CFR §720.30(h)(7). In this clarification, the Agency states that an excluded substance is one that meets each of the following three conditions:

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7);
- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

The EPA has determined that, based on the situation as you have presented it, the ion-exchange reactions of treated [SUBJECT MATERIAL] products as described in your letter are intended solely to enhance the physicochemical characteristics (including, but not limited to, the physicochemical characteristic of water fastness) of the product for which you have commercial intent. These reactions are to impart certain physicochemical properties to the product or product mixture by modifying the product's surface characteristics rather than to produce the substance itself. Therefore, the Agency considers that salts A and C, and acid B are excluded from PMN at 40 CFR §720(h)(7). Additionally, the salt A and acid B [SUBJECT MATERIAL]s do not constitute isolated intermediates in the production of salt C, as that term is used in determining whether a substance is "new" under the TSCA, so the TSCA status of salt A and acid B as exempt from PMN reporting, for our purposes, does not change.

This is based on the Agency's understanding that the reactions to form Substances A, B, and C do not provide primary properties of the product formulation. However, please be advised that, should the salt/acid form of the [SUBJECT MATERIAL] function to provide primary

properties to your product and/or you market your product as a chemical substance whose primary commercial purpose is to function independently as a salt/acid, the exclusion at 40 CFR § 720.30(h)(7) would no longer be applicable.

I hope this letter adequately responds to your request. If you have remaining questions, feel free to contact Nancy Vogel of my staff on 202-260-4183.

Sincerely,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch

3477

Mr. YYY

Re: PNC 3477

Dear Mr YYY

This responds to your letter of 31 March 1998, asking the Agency to consider whether the exemption from premanufacture notice ("PMN") found at 40 Code of Federal Regulations ("CFR") §720.30(h)(7) can apply to a treated [Chemical Material] made by your client, the [YOUR CLIENT].

You have described your client's situation as follows: [YOUR CLIENT] has developed, and is now doing research and development work on, a product which is a [Chemical Material] colorant to the surface of which sodium PPPP groups have been attached. The sodium PPPP functionality is charged, similarly to the surface treatments described in previous communications to EPA about [YOUR CLIENT] [Chemical Material]s, and because charged makes the [Chemical Material] disperse spontaneously in water. The surface treatments described in previous letters, however, are intended to remain charged in use. This can pose a problem as [Chemical Material] with a surface treatment which remains charged will precipitate from a wet coating at different rates than will resins and polymers which are also present, leading to unevenly dispersed coating when they have dried and poor color characteristics.

The value of the sodium PPPP group is that buyers of the material can covalently react it with base to produce UUUU groups, which will then react in the presence of water to produce 2-hydroxyUUUU, which are uncharged. The uncharged 2-UUUU-[Chemical Material] then associates closely with resins and polymers which are present, and remains evenly dispersed as it dries, yielding better color properties.

You asked that EPA agree with [YOUR CLIENT]'s interpretation that the product with attached sodium PPPPP groups on the surface of the [Chemical Material] can be considered to be a modification of the surface properties of the [Chemical Material], and thus exempt from PMN under 40 Code of Federal Regulations (CFR) §720(h)(7).

The Agency disagrees with [YOUR CLIENT]'s interpretation in this matter. [YOUR CLIENT] is adding reactive functional groups to the [Chemical Material] and making a new chemical substance. Based on your description, it is the Agency's understanding that the substance formed provides one of the primary properties (reversible charge) of the product

formulation, and that it does so by formation of a covalent bond. It requires notification to the Agency, either as a PMN or for one of the possible exemptions. The exclusion at 40 CFR § 720.30(h)(7) would not be applicable.

You asked further whether the (h)(7) exemption from PMN would apply for substances which might be formed as reaction products of sodium PPPP [Chemical Material] with other coating formulation components, in the event that the (h)(7) exemption did NOT apply to the sodium PPPP-functional [Chemical Material]. You stated that these substances are neither intentionally synthesized nor necessary to the function of the product(s). Based on your description, such substances might be excluded from PMN at 40 CFR §720.30(h)(1), as impurities, or (h)(2), as byproducts - because they are not desired and do not provide primary properties. Please feel free to call Mr. David Schutz of my staff on 202-260-8994 with any question on this matter.

Sincerely,

Rebecca Cool, Chief
New Chemicals Prenotice Branch (7405)

3542

Ms [LETTER WRITER]
[YOUR COMPANY] North America, Inc.

Re: PC 3542

Dear Ms [LETTER WRITER]:

This letter responds to your letter dated 23 September 1998 to Dave Schutz of my staff, in which you raised several questions relating to nomenclature for listing substances on the Toxic Substances Control Act ("TSCA") Chemical Substances Inventory ("Inventory"), as well as one question regarding application of the exemption from premanufacture notification ("PMN") requirements under §5 of the TSCA described at 40 Code of Federal Regulations ("CFR") §720.30(h)(7) ("(h)(7)"). I regret that this answer is so late in coming to you: my staff had drafted a response at the time, but we can find no record that it was sent. I understand that we have already given you our response in a meeting, but for your records we are sending you this letter at this time.

After your letter was sent you told Mr. Schutz by telephone that you wanted a meeting with the Agency to seek a change in the Agency position on your nomenclature issues (referenced as "Position 1" through "Position 4"), and asked that response to your letter be held back until it could reflect the Agency response to such a meeting. Nomenclature questions are generally

handled by the Inventory Group within the Industrial Chemistry Branch in the Economics, Exposure, and Technology Division (Mail Stop 7406 USEPA, 401 M Street, SW Washington, DC 20460). We are therefore not responding to the nomenclature issues you raised in this letter, and are responding only to your questions on the "(h)(7)" exemption

Your (h)(7) questions ("position 5") relate to XXXXXX-based soaps produced by [YOUR COMPANY] for incorporation into lubricants used when drawing metal rod into wire. You state that [YOUR COMPANY] believes that each of these substances is either listed on the TSCA Inventory or is covered by an exemption from reporting. You described your situation in regard to 40 CFR \$720.30(h)(7) generally as follows: many different lubricant soaps are made, one or more of the soaps is/are then blended with other additives to complete the lubricant formulation. In general, such a blending is expected to form a mixture, with no reaction between the soap(s) and the other additives; however one of the frequently-used additives is elemental [XXX], which when blended with an unsaturated soap probably does add at the double bond. You state that [YOUR COMPANY] has not regarded the formation of such a [XXX]ized soap to generate a reportable substance in the past, as the [XXX] is added to provide lubrication performance properties at extreme pressure (which you have believed to be appropriately covered by the list of performance characteristics covered in the (h)(7) exemption), and because similar saturated soaps function as intended without the formation of the bond to [XXX].

The Agency has concluded that, based on the situation as you describe it, the [XXX]ized soaps are not manufactured for distribution in commerce as chemical substances *per se*, and they have no commercial purpose separate from that of the mixture of which they are part. The situation as you describe it fits within the terms of 40 CFR \$720.30(h)(7)(i), and therefore [YOUR COMPANY] is correct that the exemption is applicable to the formation of the [XXX]ized soaps. However, if a [XXX]ized soap is intentionally imported or manufactured and commercially distributed in the United States as a chemical substance providing primary properties, then it would be subject to PMN reporting if it is not already listed on the Toxic Substances Control Act Inventory.

The appropriate role of the Prenotice Group in regard to your nomenclature questions ("Position 1" through "Position 4") is to communicate existing policy to you. Since you stated that you wanted to seek a change in existing policy, the appropriate action was to contact the Inventory Group in the Industrial Chemistry Branch. If you have any questions on this matter, please contact Dave Schutz on 202 260 8994.

Sincerely,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch

3574

Ms [LETTER WRITER]
[YOUR COMPANY] Chemicals, Inc

Re: Prenotice Communication 3574

Dear Ms [LETTER WRITER]:

On 22 November 2000 you sent Dave Schutz of my staff copies of two letters which your company had previously sent to the Prenotice Group in the New Chemicals Program. The letters were originally sent on April 17, 1998 and September 16, 1998. Additionally, the Agency sent a request for further information on December 2, 1998 and [YOUR COMPANY] sent a response on December 21, 1998. In this correspondence [YOUR COMPANY] has sought interpretations of the appropriateness of exemption from the requirement for premanufacture notice found at section 5 of the Toxic Substances Control Act ('TSCA'). This letter will respond to the issues raised in this correspondence.

In your April 17 letter you discussed your company's and the Agency's interpretation of the exemption at 40 Code of Federal Regulations ('CFR') §720.30(h)(7). In its INDUSTRIAL PROCESS products, your company had considered itself to be a formulator of mixtures of chemical substances rather than a manufacturer. Your company has reconsidered this position in its TSCA Audit in the context of the Agency's issuance of (h)(7) guidance on June 29, 1994 and your April 17 letter requested Agency determinations of the appropriateness of (h)(7) exemptions for sixteen specific chemical substances for which [YOUR COMPANY] (predecessor company to [YOUR COMPANY]) filed PMNs concurrent with the submission of the April letter.

3662

Mr. [Ccc]

Re: PC 3662

Dear Mr. [Ccc]:

This letter responds to yours of April 7, 1997, sent to Mary Cushmac, who was then a member of the New Chemicals Program staff, and re-sent by facsimile on March 5, 1999, to Dave Schutz of my staff. I regret that your letter did not get an answer at the time you sent it: as you may be aware, Ms Cushmac left the program in a reorganization during that period and some assignments did not get transferred to other staff.

In your letter, you asked that the Agency confirm your interpretation that substances not on the Toxic Substances Control Act (TSCA) Inventory (Inventory) which might be formed as a result of the addition to your client's PRODUCT of a commercial product (basically, XXXX) marketed as a "PRODUCT extender", and which, in your words, has an effect on the "[MEASURABLE PROPERTY]" properties of the PRODUCT, could be considered to be exempt from premanufacture notice (PMN) requirements under §5 of the TSCA as falling within the purview of 40 Code of Federal Regulations (CFR) §720.30(h)(7)(ii): "...intended solely to impart a specific physiochemical characteristic..."

From your description of "[MEASURABLE PROPERTY]", the Agency has determined that the desired properties of the PRODUCT extender are appropriately covered by "plasticizer", and thus can be excluded from reporting under 40 CFR §720.30(h)(7)(i). Based on the facts as you stated them, you have appropriately considered the three criteria identified in our June 29, 1994 clarification of the (h)(7) exemption in considering whether any non-Inventory substances which may be formed upon addition of the PRODUCT extender are covered by the exemption. If you have further questions, please contact Dave Schutz of my staff, on 202 260 8994.

Sincerely

Rebecca S. Cool
Chief, New Chemicals Prenotice Branch
Chemical Control Division

3591 PC 3591FU
Dear Ms HHHH:

This letter responds to your facsimiles of 27 May 1999, 30 July 1999, and 3 August 1999. In your letter, you described your company's manufacture of an ink product, which is a mixture of several chemical substances. You asked that the Agency confirm your opinion that a material which you describe as "substance A", and which you describe as serving as part of the vehicle component of the ink product, is exempt from premanufacture notification (PMN) otherwise required by Section 5 of the Toxic Substances Control Act (TSCA) under the exemption at 40 Code of Federal Regulations (CFR) §720.30(h)(7) as a modifier of physicochemical properties without separate commercial use. The Agency does not agree: substance A needs to be the subject of a PMN if it is to be imported into the United States as a component of your ink product.

You note that the vehicle component of the ink carries the pigment and gives it desired physicochemical properties (disperses pigment, adjusts viscosity, fixes pigment to paper, etc.) However, you also state that substance A is made outside of the ink product and added to the mixture after it is synthesized.

The Environmental Protection Agency (EPA, Agency) has issued guidance, in the form of a June 29, 1994 letter from Joseph Carra, Deputy Director of the Office of Pollution

Prevention and Toxics (OPPT) on the exclusion found at 40 CFR §720.30(h)(7) (copy attached). In this clarification, the Agency states that an excluded substance is one that meets each of the following three conditions:

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7);
- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

The EPA has determined that the situation you have presented meets neither condition 2 nor condition 3: when you formulate substance A outside of the ink mixture and add it to the ink mixture, you are distributing it in commerce as that term is used in the TSCA. Therefore, the properties it provides are its primary properties (even though its properties are not the primary properties of the ink), and it is being distributed for a commercial purpose by making it and adding it to the ink mixture.

If you have further questions, please contact Dave Schutz of my staff, on 202 260 8994.

Sincerely

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch
7405 Chemical Control Division

3716

PC 3716

Dear Mr YYY:

This letter responds to your letter dated 26 January 1999, sent to Dave Schutz of my staff. In that letter, you describe the formation of [FLOCCULANT PRODUCT] (CAS NUMBER) in the blend chest of a papermaking operation. You describe the situation as follows: [intermediate 1 for flocculant] is added to pulp slurry in a process tank ("blend chest") in the papermaking process. After blending, the material is moved

to another blend chest, where [intermediate 2 for flocculant]s are added and the [intermediate 1 for flocculant] and [intermediate 2 for flocculant] can react. The pulp slurry containing [FLOCCULANT PRODUCT] is then carried onto wire screens, where the material is dewatered and made into paper.

You ask whether a person is required to report this material under the Inventory Update Rule ("IUR") at 40 Code of Federal Regulations ("CFR") §710.28, and specifically if it is exempted from IUR under 40 CFR §710.4(d)(7) or §710.4(d)(5). Actually, the IUR at 40 CFR §710.28 excludes persons manufacturing substances which are excluded from premanufacture notice ("PMN") requirements at 40 CFR §§720.30(g) (byproducts) or (h) (substances without separate commercial intent, including at (h)(7) those formed when a flocculant acts as intended and at (h)(5) those formed during end use of a chemical substance) from the requirement to report under the IUR. As the material is not a byproduct, 40 CFR §720.30(h) is the section to consider in determining whether [FLOCCULANT PRODUCT] is excluded from the IUR requirement at 40 CFR §710.28.

Though [intermediate 1 for flocculant] is a flocculant, the [FLOCCULANT PRODUCT] formed from [intermediate 1 for flocculant] and [intermediate 2 for flocculant] is not itself a flocculant in any ordinary sense of the term. Its synthesis is intentional, and it has a desired function in the final product paper. Thus the Agency has determined that the exemption at §720.30(h)(7) is not applicable to [FLOCCULANT PRODUCT] under the conditions you have described.

The Agency agrees, however, that 40 CFR §720.30(h)(5), which excludes any chemical substance which is the result of a reaction that may occur upon end use of other chemical substances, mixtures, or articles, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate, is applicable to [FLOCCULANT PRODUCT] which forms in a paper blend tank in the manner described above. Since the (h)(5) exemption is applicable, your client need not report the [FLOCCULANT PRODUCT] under the Inventory Update Rule.

Please feel free to call Mr. David Schutz of my staff on 202-260-8994 with any question on this matter.

Sincerely,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch (7405)

3745

Mr. YYY

Re: Prenotice Communication 3745

Dear Mr. YYY:

This letter responds to your letter of 31 March 1998, re-sent to the Agency in June, 1999. You asked that the Environmental Protection Agency (EPA, Agency) determine whether your client's manufacture of a treated [SUBJECT MATERIAL] can be considered to be covered by the exemption to the requirement for premanufacture notification ("PMN") found at 40 Code of Federal Regulations (CFR) §720.30(h)(7). We have reviewed the information you provided and determined that the material does not meet the exemption criteria at 40 CFR §720.30(h)(7).

In your letter, you stated that your client ([YOUR COMPANY] Corporation, [YOUR COMPANY]) is developing a [SUBJECT MATERIAL] treated with [SSSS] groups. The purpose of the treatment is to give the material a negative charge. Due to the negative charge, [SSSS] [SUBJECT MATERIAL] disperses well in aqueous material. [YOUR COMPANY] also uses other treatments to make salts of, and thus create desired use characteristics for, its [SUBJECT MATERIAL]s. Your firm described another situation of treating [SUBJECT MATERIAL] to give it surface charge on behalf of [YOUR COMPANY] in a letter to which the Agency gave the prenotice communication (PC) number 3345. In PC 3345, you described a [SUBJECT MATERIAL] product treated with ion exchange reactions to enhance certain secondary properties (for example, water fastness) of the substance for which [YOUR COMPANY] had commercial intent. You stated that the substance functions as a colorant regardless of whether it is in salt form and that it was not [YOUR COMPANY]'s intention in forming the salt of [SUBJECT MATERIAL] which results from these reactions, to change its properties as a colorant. In response, the Agency concluded that synthesis of that material was a surface treatment whose purpose was to produce a physicochemical characteristic which was not the primary property of the [SUBJECT MATERIAL]. Thus, in its response to the earlier communication, the Agency was able to make the three determinations necessary for a material to be exempt from notification under 40 CFR §720.30(h)(7):

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) (the types are: stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent or other chemical substance, which is intended solely to impart a specific physicochemical characteristic);
- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

The treatment of [SUBJECT MATERIAL] described in PC3345, however, can

under some circumstances lead to poor color quality after the material dries. You have identified as a problem a failure of the negatively charged material to intimately associate with the resins and polymers in the wet coating formulation, and consequent precipitation of the treated [SUBJECT MATERIAL] at a different rate from the rest of the formulation during drying, leading to uneven dispersion and poor color characteristics. To deal with this problem, as described in your current letter, [YOUR COMPANY] has determined that it can attach [SSSS] to the [SUBJECT MATERIAL] to enable good dispersion in aqueous material. The special value of attaching [SSSS] to the [SUBJECT MATERIAL] is that, once it is dispersed in the coating, it can be chemically changed by adding base to the coating mixture, eliminating the QQQQ and leaving [SUBJECT MATERIAL] with a surface coating of BBBB groups, which then react with water to produce uncharged 2-hydroxyBBBBB groups. Once the surface of the [SUBJECT MATERIAL] is uncharged, it will intimately associate with the resins and polymers in the wet coating formulation, and the color characteristics, upon drying, are improved. You now ask that the Agency agree with your interpretation that the production of the [SSSS] [SUBJECT MATERIAL], followed by conversion to 2-hydroxyBBBBB [SUBJECT MATERIAL], is exempt from PMN notification, similarly to the material discussed in PC 3345, as a surface treatment whose purpose was to produce a physicochemical characteristic which was not the primary property of the [SUBJECT MATERIAL].

The Agency disagrees. [SSSS] [SUBJECT MATERIAL] fails both conditions 2 and 3, above. Based on your description, it functions to provide primary properties that determine the use of the product or product mixture distributed in commerce (charge-based dispersibility, followed by chemical conversion to an uncharged state), and it is itself the substance intended for distribution in commerce.

You further asked whether the exemption at 40 CFR §720.30(h)(7) is, or is not, applicable to the [SSSS] [SUBJECT MATERIAL] in its possible reactions with water and other nucleophilic groups in coatings systems, even though it was not the manufacturer's intent that such reactions occur and such reactions were not necessary for the material to function as intended. In either case, the exemption at 40 CFR §720.30(h)(1) for impurities would exempt such reaction products from PMN. The 2-hydroxyBBBBB [SUBJECT MATERIAL] formed by addition of base to the coating mixture including [SSSS] [SUBJECT MATERIAL] would also be exempted from PMN requirements under 40 CFR §720(h)(7) as a substance formed when a precipitation inhibitor (the base) functions as intended.

If you have any questions about this letter, please contact my staff member Dave Schutz on 202-260-8994.

Sincerely,

Roy Seidenstein
Chief (Acting)
New Chemicals Prenotice Branch
Chemical Control Division - 7405

Ms hhhhh

Re: PC 3870

Dear Ms hhhhh:

This letter responds to your letter dated 23 November 1999 and sent to Dave Schutz of my staff, in which you asked that the Environmental Protection Agency ("EPA", "Agency") agree with your view that a substance which you believe to be formed when your firm makes a mixture of other substances is exempt from the premanufacture notification ("PMN") requirements under §5 of the Toxic Substances Control Act ("TSCA") as described at 40 Code of Federal Regulations ("CFR") §720.30(h)(7) ("(h)(7)").

Your (h)(7) question relates to a CCCCC solution for use in silicon wafer production. The active ingredient is [proprietary identity] acid, buffered with a mix of [WEAK BASE] and [WEAK ACID]. It is your belief that some of the [base] in the solution forms a salt with the [proprietary identity] acid, forming some form of [SALT OF THE PROPRIETARY ACID]. You state that this salt formation, if it occurs, may increase solubility of the [proprietary identity] acid, but that it does not appear to increase the effectiveness of the mixtures for CCCCC, and you discuss the experiments you have done in support of that view. You have not stated explicitly, but it seems clear from your letter that there is no specific intent on the part of your company to manufacture the [SALT OF THE PROPRIETARY ACID]. You state that the formation of the [SALT OF THE PROPRIETARY ACID] is incidental to the buffering action of the [WEAK BASE]/[WEAK ACID] mixture, and that the [SALT OF THE PROPRIETARY ACID] has no separate commercial value.

The Agency has concluded that, based on the situation as you describe it, the [SALT OF THE PROPRIETARY ACID] is not manufactured for distribution in commerce as a chemical substance *per se*, and it has no commercial purpose separate from that of the mixture of which it is a part. The situation as you describe it fits within the terms of 40 CFR §720.30(h)(7), and therefore YOUR FIRM is correct that the exemption is applicable to the formation of the [SALT OF THE PROPRIETARY ACID]. However, if [SALT OF THE PROPRIETARY ACID] were intentionally imported or manufactured and commercially distributed in the United States as a chemical substance providing primary properties, then it would be subject to PMN reporting if it is not already listed on the Toxic Substances Control Act Inventory.

If you have any questions on this matter, please contact my staff member Dave Schutz on 202 260 8994.

Sincerely,

Rebecca S. Cool, Chief

New Chemicals Prenotice Branch
Chemical Control Division, Mail Stop 7405

3992

Dear XXXXX:

Thank you for your letter dated XXXX, to Dave Schutz of my staff. Your letter asked whether 40 Code of Federal Regulations ("CFR") §720.30(h)(7) or (h)(6) exempts a CCCC used to strengthen XXXXXX pellets from premanufacture notification ("PMN") under §5 of the Toxic Substances Control Act ("TSCA"). The exemption at §720.30(h)(7) is unlikely to be appropriate unless the COMPONENT SUBSTANCES OF CCCC themselves are the providers of the binding function. Even if that is true, (h)(7) can be appropriate only if the CCCC forms during manufacture of the pellets. The exemption at §720.30(h)(6) is unlikely to be appropriate unless the shape of the pellets is critical to their use. However, based on the facts in your letter, it appears that the exemption at §720.30(h)(5) would cover a binder such as you describe.

In your current practice, COMPONENT SUBSTANCES OF CCCC are added to XXXXX, extruded, and heat treated. During the heat treatment, the COMPONENT SUBSTANCES OF CCCC combine with each other and form CCCC, holding the XXXXX particles together in cylindrical pellets. Neither the CCCC nor any of its COMPONENT SUBSTANCES reacts with the XXXXX. XXXXX XXXXXXXXXXX XXXXXXXX XXXXXXXX A detailed response to your questions follows:

1. Can the XXXXX be exempted from PMN through the "incidental chemical" exemption at 40 CFR §720.30(h)(7)?

As you noted, a 1994 letter from Joseph Carra, the then Deputy Director of the Office of Pollution Prevention and Toxics, provides guidance on the exclusion found at 40 CFR §720.30(h)(7). This letter states that an excluded substance is one that meets the following three criteria:

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) [those substance types are: (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic];
- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

Your purpose in adding COMPONENT SUBSTANCES OF CCCC to the XXXXX appears to be as raw materials for the CCCCC. It is the CCCCC which has the intended purpose as a binder. As raw materials for the binder CCCCC, the COMPONENT SUBSTANCES OF CCCC have neither any of the specific functions nor the general "physicochemical characteristic" function named in Criterion 1. Consequently, the exemption at §720.30(h)(7) will not apply in this case.

Please note that even if you made the CCCCC outside of the pellets and added it to the XXXXX to form pellets, the exemption at §720.30(h)(7) would still not apply. Once you made the CCCCC outside of pellet extruder, the synthesis of the CCCCC and its addition to the pellets would constitute distribution in commerce of a substance whose primary property was binding, so it would fail Criteria 2 and 3.

2. Can the cylindrical shape of the pellets allow the CCCCC to be exempted from PMN through the "article" exemption at 40 CFR §720.30(h)(6)?

An article is defined in the PMN regulations as a manufactured item for which the shape or design is necessary to its function. 40 CFR 720.3(c) defines "article" as

"...a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article..."

You describe the cylindrical shape of the pellets and suggest that they should be considered to be "articles" as defined at 40 CFR §720.3(c). The "dependent in whole or in part upon its shape or design" exemption in the regulations is to exempt a specific shape or design necessary for end use function (for example, an automobile bumper must be formed to a specific shape to be able to be bolted to the frame of the automobile for which it is made, and it must bolt to the frame to serve its function). The cylindrical shape of your pellets may well be chosen for ease of manufacture, packaging, shipping, etc. At the least, to use this exemption, you need to be able to show that the function of the XXXXXX pellets could not be attained with a different shape. If you want to make such a claim, please contact us with details and we will discuss it with you.

The "end use" exemption at 40 CFR §720.30(h)(5) appears to apply in this case.

As you describe it, your binder is a chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate. Such substances are excluded from the PMN requirements at 40 CFR §720.30(h)(5).

Similarly to the (h)(7) exemption, above, if you made the CCCCC binder outside of the pellets and added it to the pellets, the (h)(5) exemption would not apply because the synthesis of the CCCCC and its addition to the pellets would constitute distribution in commerce.

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz, of our staff, on 202-260-8994.

Sincerely Yours,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch
7405 Chemical Control Division

3904

Ms EEEEEEE

Re: Prenotice Communication 3904

Dear Ms EEEEE:

This letter responds to yours sent 10 November, 1999 to David Schutz of my staff. In your letter you raised three issues for a consulting client: whether premanufacture notification ("PMN") is required for a substance which is a salt of a material already on the Toxic Substances Control Act ("TSCA") Inventory of Chemical Substances ("Inventory"); whether your client's ability to rely on the "2 per cent rule" for a polymer containing a monomer at just under two percent by weight is lost when a subsequent chemical modification of another monomer which is a component of the polymer would raise the percent by weight of the first monomer above two percent; and whether the identity your client had assigned to a graft copolymer of [MATERIALS] is correct.

Question 1: your client makes a copolymer of [1111-ate] and [ACID NAME] acid. This substance is on the Inventory. It is soluble only in a limited range of solvents, and your client wants to sell it as an aqueous solution. To make the material soluble in water, the client needs to convert the acid to an ionized form. You gave as an example production of its ammonium salt, using ammonium hydroxide. You asked us to confirm that this salt formation provided a primary property of the material, and thus requires a PMN.

You are correct. The Environmental Protection Agency (EPA, Agency) has issued guidance, in the form of a June 29, 1994 letter from Joseph Carra, Deputy Director of the Office of Pollution Prevention and Toxics (OPPT) on the exclusion found at 40 CFR §720.30(h)(7). In the 1994 clarification, the Agency stated that an excluded substance is one that meets each of the following three conditions:

- 1) the substance is formed from a chemical reaction that

involves the use of a substance of the type described under 40 CFR §720.30(h)(7);

- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

In response to your question the Agency has determined that solubility constitutes a primary property of the material under the circumstances you describe, so the material does not meet condition number 2, and that the substance is itself the one intended for distribution in commerce, so it does not meet condition number 3. Thus, to be sold it must be on the Inventory or covered by an exemption (e.g., low volume exemption or low release-low exposure exemption).

You note that a competitor of your client's is selling the same acid and giving instructions to its customers on making the identical salt to improve its solubility. You ask whether this means that the salt must be on the Confidential Inventory. It may well not: as you describe the situation, your client's competitor is not selling the salt, only the TSCA-listed acid. If the competitor's customer then makes the non-Inventory-listed salt under circumstances which are covered by an exclusion (common exclusions are those at 40 CFR §§720.30(h)(5) ("end use"), (h)(6) ("forms during manufacture of an article"), or (h)(7) (salt formation meeting the 3 criteria noted above), notification would not be required. I have described the (h)(5) and (h)(6) exclusions below:

40 CFR §720.30(h)(5) excludes from PMN requirements any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article such as an adhesive, paint, miscellaneous cleanser or other housekeeping product, fuel additive, water softening and treatment agent, photographic film, battery, match, or safety flare, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate. The exclusion at 40 CFR §720.30(h)(6) with regard to the finishing process of an article excludes chemical substances that are not manufactured for distribution in commerce as chemical substances *per se* and have no commercial purpose separate from the mixture or article of which they may be a part. This excludes chemical substances formed when a substance reacts with other substances

upon end-use of those substances by a processor. Such end-use reaction products should not be reported.

Question 2: you asked whether your client's ability to rely on the "2 per cent rule" for a polymer containing a monomer at just under two percent by weight is lost when a subsequent chemical modification of the other monomer which is a component of the polymer would raise the percent by weight of the first monomer above two percent.

Your ability to use the 2% rule is not lost under these circumstances. You are allowed to calculate for the 2% rule on an "as charged" or an "as incorporated" basis. If you calculate on an "as charged" basis, you meet the requirements of the rule. An "as charged" calculation is appropriate in this case.

Question 3 [THIS ANSWER BEGINS WITH DISCUSSION OF NAMING WHICH INCLUDES CHEMICAL IDENTITIES AND DOES NOT REFER TO (h)(7); IT HAS BEEN OMITTED] this is not nomenclature which is consistent with the Ninth Collective Index (9CI) of Chemical Abstracts Service (CAS) nomenclature rules and conventions (this definitive guide to CA nomenclature has been used since 1972). For maintaining records for compliance with the polymer exemption from premanufacture notification under TSCA §5, it is appropriate to name materials using the conventions of the 9CI. A chemical manufacturer can ensure that it has the appropriate 9CI name by requesting the name from the Inventory Expert Service of the Chemical Abstracts Service.

If you have any remaining questions on this matter, please contact Dave Schutz of my staff on 202-260-8994.

Sincerely,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch

3999

Mr. fffff

PC3999

Dear Mr. fffff:

Thank you for your letter dated May 19, 2000, to Dave Schutz of my staff. Your letter asked whether your client's products are exempt from premanufacture notification ("PMN") under §5 of the Toxic Substances Control Act ("TSCA") either

under the provisions at 40 Code of Federal Regulations ("CFR") §720.30(h)(7) or as a statutory mixture. Based on your description, your client's materials appear to meet the Agency's criteria for statutory mixtures.

You describe your client's practice as follows: your client makes two products. In each, two [MINERALS]s are mixed with two [SURFACTANT MATERIALS]s. The [SURFACTANT MATERIALS]s interact with the [MINERALS]s by surface absorption and ion exchange, and this is shown by the presence of [A SALT] in the supernatant. The products are used to thicken organic liquids. The minerals are hydrophilic, and your client's intent in adding the [SURFACTANT MATERIALS]s is to coat the surface of the minerals and move them towards hydrophobicity. You state that a mixture of [MINERALS]s works better than either [MINERALS] by itself because the [MINERALS]s pack poorly together, similarly a mixture of [SURFACTANT MATERIALS]s disperses better than either by itself. Other surfactants could serve the purpose, but those chosen are inexpensive.

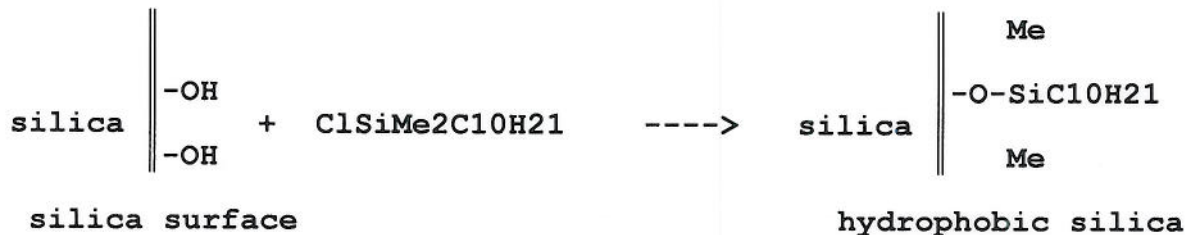
TSCA requires premanufacture notice for chemical substances, rather than for mixtures of chemical substances. Mixtures are not listed on the Inventory, nor are they subject to PMN. Any individual component of a mixture is required to be listed on the Inventory. The Agency defines 'mixture' at 40 CFR §720.3(u):

(u) Mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except "mixture" does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.

Additionally, the Agency has defined some surface treatments of chemical substances as creating "statutory mixtures", for which PMNs are not required. With the term "surface treatment" the Agency generally means the process of chemically treating the surface of a substance, the substrate, with another substance so as to enhance some physical property of the surface of the substrate or to impart chemical reactivity to the surface (i.e., to functionalize the surface chemically). The surface-treating substance adheres to the surface by van der Waal's forces, ionic bonds or covalent bonds. If the substance only alters a physical characteristic, and if the combination is not stoichiometric, then the combination of the surface treatment substance and the substrate is considered to be a

mixture of two substances, each requiring its own Inventory listing. If, however, the surface treatment is intended to impart chemical reactivity or creates a stoichiometric substance, the reaction product is required to be on the Inventory.

An example we have given for this policy is the following reaction:



In this example, the silica surface was modified by a chemical reaction to introduce a material onto the outermost layer of the silica, contributing the property of hydrophobicity to the silica without changing the bulk properties of the silica. This type of reaction is usually not stoichiometric and would not be reportable under TSCA.

Your letter states that your client's intention is to enhance a physical property of the substances, rather than to impart chemical reactivity, and you have told Mr. Schutz on the phone that the combination is not stoichiometric. Based on this characterization the Agency has determined that the substances should be considered statutory mixtures. Since they are considered mixtures rather than chemical substances, they do not merit consideration for the exemption at 40 CFR §720.30(h)(7).

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz, of our staff, on 202-260-8994.

Sincerely Yours,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch
7405 Chemical Control Division

4011

Mr. ccccc
Corporation

Dear Mr. cccccc:

Thank you for your facsimile sent 26 July 2000 to Dave Schutz, of my staff. You asked for Agency agreement that a salt formed in a [your firm] product mixture does not constitute a new substance requiring premanufacture notification ("PMN") under §5 of the Toxic Substances Control Act ("TSCA").

You have explained your situation both in your facsimile and in subsequent conversations with Mr. Schutz. It is as follows: you make a product mixture. The component of the mixture which provides its primary property is a film-forming resin. The product mixture also includes a strong organic acid which functions to lower the temperature at which crosslinking reactions occur, and an organic amine whose purpose is to stabilize the solution. You are aware that the acid and amine will neutralize, forming a salt. The acid and the amine are not mixed together before they are separately introduced into the mixture. The salt is not the source of the desired properties of the mixture. You asked that the Agency concur with your belief that the salt met the conditions for exemption from PMN under §5 of the TSCA described at 40 Code of Federal Regulations ("CFR") §702.30(h)(7).

A 1994 letter from Joseph Carra, the then Deputy Director of the Office of Pollution Prevention and Toxics, provides guidance on the exclusion found at 40 CFR §720.30(h)(7). This letter states that an excluded substance is one that meets the following three criteria:

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) functions as intended [those substance types are: (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic];
- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product

mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

You have identified your purposes in adding the amine and the acid to the mixture, and stated that the salt is incidental to those purposes. Based on your description, the salt appears to meet all three criteria identified above, and is appropriately exempted under §720.30(h)(7). You said in your letter that the amine and acid may be made up into stock solutions: such stock solutions must not be solutions of the amine plus the acid (that is, of the salt) - addition of the salt to the rest of the mixture would constitute commercial use of the salt and it would be subject to PMN.

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz, of our staff, on 202-260-8994.

Sincerely Yours,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch
7405 Chemical Control Division

4067

Ms [LETTER WRITER]

Re: Prenotice Communication 4067

Dear Ms [LETTER WRITER]:

This letter responds to your letter of 17 April, 1998, resent to David Schutz of my staff on 22 November 2000. In your letter, you requested an official Agency response on the appropriateness of your company's belief that certain salt substances found in [Your Firm] products can be exempt from Inventory listing under 40 Code of Federal Regulations (CFR) §720.30(h)(7).

As you noted, a 1994 letter from Joseph Carra, the then Deputy Director of the Office of Pollution Prevention and Toxics, provides guidance on the exclusion found at 40 CFR §720.30(h)(7). This letter states that an excluded substance is one that meets the following three criteria:

1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) [those substance types are: (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent] and which functions as intended, or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic.

2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,

3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

In general, in responding to your request, if a substance on which you requested guidance must be in salt form for [Your Firm] or its customers to use it at all, we have determined that it is reportable, but if the salt is formed only to facilitate the substance's use or as an incidental result of the presence of other substances and is not required for the substance to fulfil its primary purpose it need not be reported. We also want to clarify the effect of criterion 3, above: if a material is made separately from a mixture and then added to that mixture, that is "distribution in commerce" as the term is used in TSCA (there are a few situations in which making a material separately may not trigger a reporting requirement.) This letter will discuss your substances in the order you presented them.

1. Reaction between acids and bases - Addition of basic [INDUSTRIAL PROCESS] additives to acidic solution.

You describe situations in which organic bases are added to a [INDUSTRIAL PROCESS] solution in which a low pH has been obtained by addition of a strong acid. The base is thus protonated, but it would be soluble whether or not the pH was lowered - the pH adjustment was undertaken either to make soluble another component of the [INDUSTRIAL PROCESS] solution

or to make the solution compatible with the pH of a solution to which it will be added. You stated your position that in this case the reaction between the strong acid and the amine does not result in a substance which functions to provide a primary property of the product. Based on the facts as you have described them, the Agency agrees that the protonated base satisfies all three conditions identified in the Carra letter.

2. Reaction between acids and bases - Neutralization of [BASE] with [ACID1] and [ACID2].

You describe a formulation of [BASE], [ACID 1], [ACID 2], and [XXXX] in water, used to clean printed circuit boards. You expect that [BASE] [SALT 1 or 2] may form, but state that neither serves any function in the product. Based on the facts as you have described them, the Agency agrees that any [BASE] [SALT 1 or 2] formed satisfy all three conditions identified in the Carra letter, and need not be the subjects of PMN due to this synthesis.

3. Reaction between acids and bases - Acid and base reaction in multicomponent solution.

You describe a number of [Your Firm] [INDUSTRIAL PROCESS] bath additive products in which weak acids are partially or fully neutralized with base. These weak acids function as buffers and may in some cases also function as chelating agents with metals in the [INDUSTRIAL PROCESS] bath. You state that the acid base reactions which occur in these formulations produce an often bewildering variety of substances which do not function to provide the primary properties of the [INDUSTRIAL PROCESS] bath products. The Agency agrees with your position that the acid base reaction products which are formed are incidental to the preparation of the [INDUSTRIAL PROCESS] bath additive and that, in the absence of specific intent to manufacture a non-Inventory substance for a purpose other than as a buffer or chelator, the (h) (7) exemption applies to these materials.

4. Reaction between acids and bases - Addition of ammonia to partially neutralized weak acids.

You describe addition of ammonia to the [INDUSTRIAL PROCESS] bath additive products described above. The ammonia functions as a ligand for [METALS] in the bath. It is reasonable to expect that, when the ammonia is present with partially neutralized weak acids like those discussed in (3), above, that ammonium salts will form, however the intended function of the ammonia is not as a neutralizer for the acids; it is as a ligand. In fact, the ammonia must dissociate from the acid to function as a ligand. The salts do not provide any desired properties in the solution. The Agency agrees with your position that such salts meet all three of the criteria

identified in the Carra letter and are exempt from premanufacture notice under section 5 of TSCA.

5. Reaction between acids and bases - Acid and base premixed to aid in metering performance additives.

You describe several products which are intended as performance additives (EXAMPLES) for [INDUSTRIAL PROCESS] baths. The materials you are interested in delivering to the [INDUSTRIAL PROCESS] baths are organic substances which include an acidic group, and which need to be added to the [INDUSTRIAL PROCESS] bath in small and measured quantities. These materials are sometimes not very soluble. To facilitate adding these performance additive materials in small and exact amounts, you make aqueous premixes of the materials. Either to speed the dissolution of the materials or to enable the materials to dissolve fully, your company often adds base to the premixes. This makes the materials into highly soluble salts, which are then metered into the [INDUSTRIAL PROCESS] baths. You state that the materials may or may not remain in salt form when in the final [INDUSTRIAL PROCESS] solutions; it's not important to product performance. The materials could be added as neat dry acids, measured by weight, and the salt formation is incidental to allowing them to be metered as liquids. You stated your company's belief that, since the primary properties of these materials were as performance additives and these properties in no way depended on their having been made into salts, they were exempt from premanufacture notification through 40 CFR §720.30(h)(7). This is not correct. These materials are being manufactured separately from the [INDUSTRIAL PROCESS] baths to which they are intended to be added, consequently they fail the third criterion of the Carra letter and are themselves the materials being distributed in commerce when they are metered into the [INDUSTRIAL PROCESS] solutions. Additionally, you note that "an equivalent or more of base" is added - when the stoichiometry of the reaction is a consideration it strongly suggests that an (h)(7) exclusion is not appropriate.

6. Reaction between acids and bases - Acid and base premixed to aid in accurate measurement and to enhance solubility in formulations.

For the reasons discussed above - separate manufacture - these materials fail the third criterion of the Carra letter. Since the materials must be in salt form to be soluble in the mixture to serve their function, this case fails the second criterion as well - the substance does in this case function to provide the primary properties that determine the use of the product or product mixture.

7. Reaction between acids and bases - Acid/base reactions to enhance solubility of formulations

Since the materials must be in salt form to be soluble in the mixture to serve their function, this case fails the second criterion above - the substance does in this case (like that in #6) function to provide the primary properties that determine the use of the product or product mixture.

8. Reaction between acids and bases - Neutralization of [ACID]acid with sodium hydroxide

For the reasons discussed at #5 - separate manufacture - this material fails the third criterion in the Carra letter.

9. Reaction between acids and bases - Neutralization of [BASE 3].

I noted earlier in this letter that making a material separately may not trigger a reporting requirement in certain limited circumstances. You have described a situation which is similar enough to one of those circumstances that it's worth showing the distinction in detail: you describe neutralization of [BASE 3] which is done for two purposes: to reduce the vapor pressure/combustibility of the material for transport, and to enhance the solubility of the material when it is added to the intended product mixture. The Agency has in the past allowed the (h)(7) exclusion to cover pH adjustment of a material (resulting in salt formation) for transport, when that adjustment was for the purpose of meeting a Department of Transportation requirement on transport of hazardous materials and the original material was reconstituted after the salt was received. The situation you have described here does not fit this scenario - there is no intent to reconstitute the original material, rather the salt is used, and its solubility is improved when added to the intended product mixture. Thus, for the reasons discussed at #5 - separate manufacture - this material fails the third criterion in the Carra letter.

10. Reaction between acids and bases: reaction of [BASE 4] with Acid

You describe [Your Firm]'s importation for use in [INDUSTRIAL PROCESS] baths of solutions of [ACID]acid which have been pH adjusted before import with, in one case, potassium hydroxide and sulfuric acid and, in a second case, with potassium hydroxide followed by a later addition in the US of sulfuric acid. You state that the desired property of the material is the chelating properties of the [ACID]acid when added to the product, not any property specific to the salts formed when making its pH compatible with that of the [INDUSTRIAL PROCESS] bath. This material need not be notified before manufacture: if a new chemical substance is formed when a pH adjuster is included in a product and functions as intended, and the pH adjuster is not the substance itself, the substance formed is excluded from PMN at 40 CFR 720.30 (h)(7).

11. Reaction between Acids and Salts: Addition of an Organic Acid to an Acidic Formulation

You describe the addition of [salts] to very acidic [INDUSTRIAL PROCESS] bath formulations. The salts are solid, neutral materials, thus easy to handle. These materials function as [improve the properties] in the [INDUSTRIAL PROCESS] baths, and you state that their function is the same whether they are in free acid or salt form, so it is your view that the conversion from salt to acid does not provide a primary property. You asked that the Agency confirm your belief that, under the criteria of the (h)(7) exemption, the expected formation of an acid in the [INDUSTRIAL PROCESS] bath from one of these salts is not subject to the PMN reporting requirement. Based on the situation you have described, you are correct that you have no PMN obligation for these acids, however it is not the (h)(7) exemption which excuses you. The (h)(7) exemption covers substances formed due to the use of a pH neutralizer, however this acid, if a non-Inventory substance, forms at very low pH levels and cannot be seen as in the "neutral" range. Further, the acids, by your description, provide the same primary property as is provided by the salts - their function is not diminished by conversion to acids. The exemption at 40 CFR §720.30(h)(5), however, excludes from PMN requirements any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate. Since use of the salt in the [INDUSTRIAL PROCESS] bath is its end use, and the acid is not intentionally manufactured in this case, based on the (h)(5) exemption, these materials are not subject to the PMN reporting requirements.

12. Chelating Agents and Metals

You have described several situations in which chelating agents are incorporated into formulations for the [INDUSTRIAL PROCESS] industry. These formulations contain metals, and in some of your examples you expect the metals to be chelated at least to some extent by the agents in the formulations as shipped by your company. In no case is chelation of metal by the agents sought before the material is added to the [INDUSTRIAL PROCESS] bath, but you are aware that chelation will in some cases occur. In all cases, the chelating agents are intended to protect metals from precipitating out of the [INDUSTRIAL PROCESS] baths before they coat articles in the baths. Your company's view has been that the absence of intent to chelate the metals in the formulations as they are shipped from your facilities, and before they are added to the [INDUSTRIAL PROCESS] baths, removes the chelating agents from the purview of Section 5 of TSCA under the exemption for chelating agents at 40 CFR §720.30(h)(7). Your customers are not buying the material based on the presence of metal-chelate complexes in the formulations as received. Based on the

situation as you describe it, you are correct that there is no need for a PMN because the metal-chelate complex neither provides primary properties that determine the use of the product, nor is it itself the substance intended for distribution in commerce, and it involved a chelating agent functioning as intended, so is exempt under 40 CFR §720.30(h)(7).

13. Interactions of Weak Chelating Agents with Metals

You describe use of so-called "weak" chelating agents in [INDUSTRIAL PROCESS] bath formulations. These materials are intended to serve several functions, including chelation of metals as well as, [PROCESS IMPROVEMENT FUNCTIONS], e.g., in the [INDUSTRIAL PROCESS] baths. The formulations sent from your company to the [INDUSTRIAL PROCESS] users are not intended to contain metal-chelate complexes, though you are aware that they form in some cases. Your customers are not buying the material based on the presence of metal-chelate complexes in the formulations as received. And you suggest that this is an example of a chelating agent functioning as intended, thus exempt from PMN under the exemption for chelating agents at 40 CFR §720.30(h)(7). Based on the situation as you describe it, you are correct that there is no need for a PMN because the metal-chelate complex neither provides primary properties that determine the use of the product, nor is it itself the substance intended for distribution in commerce, and it involved a chelating agent functioning as intended, so is exempt under 40 CFR §720.30(h)(7).

14. Metal Salt and Chelating Agent Pre-mixed

You describe several aqueous based products which are intended as performance additives for final [INDUSTRIAL PROCESS] baths. The materials you are interested in delivering to the [INDUSTRIAL PROCESS] baths are metal salts which need to be added to the [INDUSTRIAL PROCESS] bath in small and measured quantities. To facilitate adding these performance additive materials in small and exact amounts, you make aqueous premixes of the materials. To speed the dissolution of the materials, your company often adds a chelator (XXX) to the premixes. This enables the salts to be metered into the [INDUSTRIAL PROCESS] baths. You state that the materials may or may not remain chelated when in the final [INDUSTRIAL PROCESS] solutions; it's not important to product performance. The materials could be added as neat dry salts, measured by weight, and the chelation is incidental to allowing them to be metered as liquids. You stated your company's belief that, since the primary properties of these materials were as performance additives and these properties in no way depended on their having been chelated, they were exempt from premanufacture notification through 40 CFR §720.30(h)(7). This is not correct. You are metering these chelated materials (for ease in measurement), so you have intent to make them. These materials are being manufactured separately

from the [INDUSTRIAL PROCESS] baths to which they are intended to be added, consequently they fail the third criterion of the Carra letter and are themselves the materials being distributed in commerce when they are metered into the [INDUSTRIAL PROCESS] solutions.

15. Chelating Agent Used to Prevent Precipitation of Metals from a Formulation Solution

You have described several situations in which chelating agents are used to keep metals in a formulation solution from precipitating between preparation of the solution and incorporation into a [INDUSTRIAL PROCESS] bath. These situations differ from #14, above, in that the metal-chelate complex is not being made for a purpose (in #14, ease of precision metering) other than simple keeping the metal in solution. The situations you describe as Examples 1-3 do not differ from each other in ways which are important for this determination: as you have described them, they are cases of chelating agents functioning as intended and they meet all three criteria identified in the Carra letter. Each is exempt from PMN under the (h)(7) criteria.

16. Assembly of Weak [TTTT] Complex in Solution and 17. Assembly of [rrrr] Complex in Solution

You have identified two situations each involving the preparation of a formulated [INDUSTRIAL PROCESS] bath additive. In each case, you expect that a complex between a metal and other components of the [INDUSTRIAL PROCESS] bath additive will form, but the intent is to produce a [INDUSTRIAL PROCESS] additive with end-use functions, rather than to form a particular complex. The complex is not isolated in either case, nor can it be clearly identified. Your position has been that the complex formation in each formulation is incidental to the preparation of the [INDUSTRIAL PROCESS] bath additives, that there is no particular intent to make these complexes, but that these additives optimize the performance of the [INDUSTRIAL PROCESS] bath additives, and that the (h)(7) exemption is appropriate. Though you have not asserted that the complexing material fits any of the specific categories of exemptable materials identified at 40 CFR 720.30(h)(7)(i), each can be seen as fitting at 40 CFR 720.30(h)(7)(ii) as a chemical substance, which is intended solely to impart a specific physicochemical characteristic. Thus, you are correct that PMN is not required for these complexes.

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz on 202-260-8994.

Sincerely Yours,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch

4153

Mr. YYY

Re: PC-4153

Dear Mr. YYY:

This letter responds to your letter dated 22 May 2001, and re-sent by [uuuu] of your office on 4 June 2001, in which you asked that the Agency provide a written opinion on whether the [OOO][NNN] salts, as made by a client of your firm, are exempted from premanufacture notice ("PMN") requirements by 40 Code of Federal Regulations ("CFR") §720.30(h)(7) ("(h)(7)").

In your letter, you state that, even if the (h)(7) exemption does not apply, your client had believed it applicable and would, if notice is required, expect to submit the PMN under the provisions described in EPA's June 29, 1994 letter of clarification on (h)(7) sent by Joseph H. Carra, the then Deputy Director of the Office of Pollution Prevention and Toxics ("the Carra letter").

You describe your client's situation as follows: your client makes [jjj]polymer formulations. Large vessels containing product are replenished from "make-up" tanks - and in those make-up tanks [OOO] has been used since the 1950s, originally to control cross-linking in the polymerization reaction, and more recently to provide a [COLOR] color expected by buyers of the material. The pH in the make-up tanks is raised with potassium hydroxide before the material is added to the large vessels, and as a result some or all of the [OOO] is converted to the [OOO][NNN] salts. The pH is raised for purposes unrelated to conversion of the [OOO] to its [NNN] salts - you said that it is to avoid "shock" to the material in the larger vessels when the make-up solution is added. And you state that there is no commercial purpose being served - now or ever - by the presence of the [OOO] salts in the make-up material, that the salts are formed as a result of pH adjustment independently of and subsequent to the [OOO] role in terminating polymerization reactions.

You asked that the Agency concur with your belief that the salt met the conditions for exemption from premanufacture notification ("PMN") under §5 of the TSCA described at 40 Code of Federal Regulations ("CFR") §702.30(h)(7). Based on the situation you have described, and assuming that the desired color is a function of [OOO] rather than of its salts, you are correct that the [OOO] salts need not be the subject of premanufacture notice, and that they meet the criteria for exemption under (h)(7). The Carra letter provides guidance on the exclusion found at 40 CFR §720.30(h)(7). This letter states that an excluded substance is one that meets the following three criteria:

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) and which functions as intended [those substance types are: (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic];
- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

You have identified your purposes in adding the [OOO] and the potassium hydroxide to the mixture, and stated that the salt formation is incidental to those purposes. You state that the salt is not the source of the desired properties of the mixture. Based on your description, the salt appears to meet all three criteria identified above, and is exempt under §720.30(h)(7).

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz, of our staff, on 202-260-8994.

Sincerely Yours,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch
Chemical Control Division (7405)

4226

Mr. WWWWW

Re: Prenotice Communication 4226

Dear Mr. WWWWW:

This letter responds to your letters of September 26, 2001 and November 2, 2001, sent to Mr. Charles Auer, Director of the Chemical Control Division in the Office of Pollution Prevention and Toxics (OPPT). Your September letter asked for clarification of the status of several products made in the course of manufacturing "prepregs", which are flexible combinations of fabric, fiber and impregnated resins which can be formed to a shape and cured for strength and rigidity. Your client, [CLIENT] Corporation, considered its activities in manufacturing prepregs exempt from new chemical notification to the Environmental Protection Agency, based largely on the Agency's response to a [CLIENT] inquiry made in 1978; that belief has been thrown into doubt by EPA personnel during a recent inspection. Your letter asked us to address the applicability to your situation of the exemption found at 40 CFR §720.30(h)(6):

(6) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints, or any other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that occur as described elsewhere in this paragraph.

As well, your second letter, dated 2 November 2001 suggested that, if the (h)(6) exemption cited in the Agency's 1978 response is not applicable to this situation, the exemption at 40 CFR §720.30(h)(7) could be considered as well: your client had relied on the 1978 letter in believing that it qualified for exemption under (h)(6), but you laid out the case for an exemption under (h)(7) or in the alternative, that your client could have reasonably believed that it had an exemption under (h)(7). The relevant language from the exemption at (h)(7) is:

(7) Any chemical substance which results from a chemical reaction that occurs when (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or

quality control reagent functions as intended or (ii) a chemical substance, which is intended solely to impart a specific physiochemical characteristic, functions as intended.

You noted that [CLIENT] filed a premanufacture notice for the subject material in 1998 as soon as it formed an intent to market it separately from the fabric, and that notice has been approved and [CLIENT] filed a Notice of Commencement for the material in June of 1998.

The process you have described in your letter is as follows: your client purchases resins and mixes them into a material which you call "pre-cook", the precook is mixed with additional materials and impregnated into a fabric. The impregnated fabric is exposed to heat and air, partially curing the resin into the fabric, and you refer to this step as the "B stage". At this point the material is sold to its ultimate user, and the ultimate user will later use heat and pressure in a mold to form the final reinforced plastic part. As noted above, your client has believed that substances formed in this process are all exempt from premanufacture notification. In this belief, it has relied on an August 14, 1978 letter from [NAME] of the then Office of Toxic Substances of EPA to [NAME] of [CLIENT] in which the Agency stated that "...Neither the resin that you purchase and use, nor the partially polymerized substance resulting from the "B" staging, nor the resin-impregnated material that you manufacture is reportable by your firm for the Initial Inventory."

[CLIENT]'s 1978 letter to the Agency discussed the impregnation of 'catalyzed resin' into the fabric. The [CLIENT] letter does not state whether the formulation of the catalyzed resin does or does not involve the intentional synthesis of non-Inventory chemicals, nor does the letter include the term 'precook'. Also, the Agency response letter of August, 1978 does not make it clear that intentionally synthesized non-Inventory substances may not be present in the mixtures in the resin impregnated into the fabric for B staging. It is clear from your client's successful filing of a PMN on the material in 1998, though, that new materials are in fact formed in the mixtures which are then impregnated into the fabric for B staging.

To frame our response, we should clarify that both 40 Code of Federal Regulations §720.30(h)(6) and (h)(7) cover the synthesis of non-Inventory materials during manufacture of an intended product - in (h)(6) of an article and in (h)(7) of, usually, a mixture in which the physicochemical characteristic applies to the mixture and the compound providing the property is not the intended product. If a chemical substance is made separately from a mixture and then added to that mixture, that chemical substance does not qualify for the exemptions in 40 CFR 720.30(h)(6) or (h)(7). Those exemptions cover "chemical substances which result from a chemical reaction that occurs" either during the manufacture of an article, as stated in (h)(6), or when another chemical substance functions as intended for a variety of permissible uses articulated in (h)(7). Consistent with the introductory paragraph of 720.30(h), to qualify for these exemptions, the chemical substance must be created as a part of the reactions enumerated in 720.30(h). The particular chemical substances that you are inquiring about are manufactured separately from, and then added to, the articles or mixtures to which (h)(6) and (h)(7) might otherwise apply. Thus, your chemical substances do not qualify for the exemptions in 720.30(h)(6) or (h)(7). Agency approval of the 1998 PMN indicates that the pre-cook material includes deliberately synthesized non-Inventory substances, and this shows that neither the (h)(6) nor the (h)(7) exemption applies. This is consistent with the Agency's well established policy on isolated intermediates (see the March 6, 1978 Federal Register (43 FR 9256)). Policy in this matter has also been clarified in the June 29, 1994 letter from Joseph Carra, Deputy Director of OPPT, on the exclusion found at 40 CFR §720.30(h)(7).

Neither the 1978 [CLIENT] letter to the Agency, of which you have provided a copy, nor our response, is adequately clear on this limit on the application of these exemptions. If non-Inventory materials are formed either in the precook or in the course of mixing the precook with

other materials before it is impregnated into the fabric, and if those materials are of commercial value and not otherwise exempt, each must be the subject of a premanufacture notification.

In your letter of 2 November, you had anticipated that it might be the Agency position that (h)(6) did not apply, and asserted that [CLIENT] had acted in the belief that the material was covered by both the (h)(6) and (h)(7) exemptions. You noted that the Agency had issued guidance, in the form of the 1994 Carra letter, and that it is current Agency policy that persons who had, prior to the issuance of the Carra letter, been manufacturing materials in the reasonable belief that they were excluded from PMN by (h)(7) could file and continue manufacturing those materials while the substances were under review.

In your letter of 2 November, you requested that, if the Agency position was that neither (h)(6) nor (h)(7) applied, the Agency treat PMNs submitted on the material described in your letter similarly to those submitted in response to the Carra letter. Though it is the Agency position that neither the (h)(6) nor the (h)(7) exemption excludes these materials from PMN, EPA does agree that it was possible, in this case, for [CLIENT] to have believed in good faith that, if (h)(6) was not applicable, it was acting within the scope and intent of the exclusion found at 40 CFR §720.30(h)(7). Thus, the PMN (NUMBER) filed for this material can be considered to have been filed under the clarification policy based on the Carra letter. Further, if there are other substances which you believe to be similarly appropriate for consideration under this policy, the Agency invites you to describe them to us for a determination. I hope this letter adequately responds to your request. If you have remaining questions, feel free to contact Mr. Schutz of my staff at 202-564-9262.

Sincerely,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch
Chemical Control Division (7405)

4304

Ms ?
TSCA Manager

Re: Prenotice Inquiry 4304

Dear Ms ?:

This letter responds to your letter dated March 8, 2002 to Michael C. Calhoun in the Multimedia Enforcement Branch of the Office of Regulatory Enforcement ("ORE") in the Office of Enforcement and Compliance Assistance ("OECA") in the Environmental Protection Agency ("EPA"). In addition, your firm had a conference call with Michael Calhoun, Tony Ellis, and Peter Moore of ORE and Dave Schutz of my staff on April 10, 2002. Your letter suggested that a previously unidentified substance (SUBSTANCE TYPE), which is a component of a product you manufacture under the name [BRAND NAME], can qualify for an informal amnesty for substances which were once reasonably believed to be exempt from premanufacture notification ("PMN") under 40 Code of Federal Regulations ("CFR") §720.30(h)(7). Criteria for exemption were delimited to the chemical industry in a clarification letter from Joseph Carra, the then Deputy Director of the Office of Pollution Prevention and Toxics ("OPPT"), on June 29, 1994. Mr. Carra's letter provided guidance on the applicability of the (h)(7) exemption and led a number of chemical manufacturers to file PMNs with the Agency

for substances which they previously reasonably believed to be exempt. In these cases the Agency has allowed manufacture to continue while the PMNs were being reviewed, and has not pursued enforcement actions. This amnesty policy, however, is only applicable to substances which were already known to be synthesized and were reasonably believed to be exempt under 40 CFR §720.30(h)(7) prior to the issuance of the clarification letter.

OPPT has determined that your situation does not qualify for the amnesty policy associated with 40 CFR §720.30(h)(7), therefore to seek similar relief you will need to request enforcement discretion from ORE. The situation you have described in your letter does not match the one addressed by the Carra letter. Your company did not believe it was manufacturing the (SUBSTANCE TYPE) under the exemption at 40 CFR §720.30(h)(7); rather the (SUBSTANCE TYPE) was not known to be a component of [BRAND NAME] - or at least was not known to have the desirable properties you have now identified. Thus, even if you knew it was present, as far as you knew it was an impurity exempt from PMN requirements based on 40 CFR §720.30(h)(1) for chemical substances produced without a separate commercial intent during the manufacture, processing, use or disposal of another chemical substance or mixture.

Now that you have determined that the [substance type] is present and has desirable properties, it must be considered a co-product and, if not on the Inventory, is therefore subject to PMN reporting. It is a prohibited act under section 15(2) of the Toxic Substances Control Act ("TSCA") to "use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed or distributed in commerce in violation of section 5 or 6..." This means that you would be in violation if you sold any [BRAND NAME] now in stock if it was manufactured before the approval date of the Low Volume Exemption ("LVE") you filed on the material. You requested in your letter that the Agency consider the LVE submission (LVE NUMBER) submitted by your company to have been submitted under the informal amnesty. This is inappropriate, for the reasons described above.

In your April 10 conference call with Agency personnel, your firm stated that as soon as you became aware that the [substance type] was present, and was valuable to the performance of your product, you embargoed any material on hand and that you refrained from making any new material until after the LVE was approved. This was the appropriate course of action on your part. You also said that your company has quarantined material which it wants to enter into commerce. Since TSCA does not permit such manufacture or sale, this can be authorized only through exercise of EPA enforcement discretion. Enforcement discretion is an authority held by the Assistant Administrator of OECA. As discussed in the conference call, it is appropriate for you to request enforcement discretion to allow you to sell existing stocks of the material manufactured before the approval of the LVE.

Your request for enforcement discretion to sell and distribute the embargoed inventory should include the amount and location of embargoed material in your possession or control. As well, you need to include the date you became aware that the [substance type] was present in the product and valuable to its function. In general, EPA may refuse such a request if it determines that either:

1. The correct chemical identity was known to or reasonably ascertainable by the submitter when it submitted its original PMN or Form C identification for placement on the Original Inventory (that is, the submitter had failed to use due diligence in a good faith effort to correctly identify the substance); or
2. The newly identified substance may present an unreasonable risk of injury to human health or the environment.

In granting your LVE, EPA has already determined that the substance will not present an unreasonable risk of injury under the conditions of use to which you have bound yourself. Consequently, in requesting enforcement discretion in this matter, you should address (in addition to the amount, location, and date questions identified above) only criterion #1, above. Please discuss the nature of the "further technical review" conducted on [BRAND NAME] through which you identified the material's presence, and also show why it was reasonable that your (predecessor) company's original review of the product did not identify either the presence of the [substance type] or its value for the product.

Please direct your request for enforcement discretion to Michael C. Calhoun, Multimedia Enforcement Branch, Mail Stop 2248, Office of Regulatory Enforcement, Room 3118 Ariel Rios Building, Environmental Protection Agency, 1200 Pennsylvania Ave., Washington DC 20460. You can reach Mr. Calhoun by telephone on 202-564-6031. If you wish to further discuss the informal amnesty or the provisions of 40 CFR §720.30(h)(7), contact Dave Schutz of my staff on 202-564-9262.

Sincerely,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch
Mail Stop 7405M, Chemical Control Division

4359

Mr. [CORRESPONDENT]

Re: Prenotice Communication 4359

Dear Mr. [CORRESPONDENT]:

:

This letter responds to yours of 5 June 2002, in which you requested that the Environmental Protection Agency ("EPA", "Agency") concur with your determination that certain substances found in your client's fertilizer products can be exempt from listing on the Toxic Substances Control Act ("TSCA") Inventory ("Inventory"), which listing would otherwise be required under section 5 of the Toxic Substances Control Act (TSCA). You believe that the products can be exempt because they meet the criteria for exemption at 40 Code of Federal Regulations (CFR) 720.30(h)(7), in particular as they are explained in the Agency guidance on the (h)(7) exclusion in the June 29, 1994 letter from Joseph Carra, then Deputy Director of OPPT.

As you noted, the 1994 letter from Joseph Carra provides guidance on the exclusion found at 40 CFR §720.30(h)(7). This letter states that an excluded substance is one that meets the following three criteria:

- 1) The substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) and which functions as intended, or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic;

- 2) The substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) The substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

You have described two fertilizer products which are made largely from waste products and which are valued because they release [MINERALS] more slowly than do competing fertilizer products (you describe the slow portion of the fertilizer release as 'NNNN.'") In making each product, a waste product which is on the TSCA Inventory (WASTE PRODUCT) is mixed with other Inventory materials, granulated, and dried. The resultant granulated mixture consists of some substances which are on the Inventory and have fertilizer activity and some amorphous materials which are not on the Inventory and which (telephone communication) may or may not themselves have fertilizer activity, but which you see as important in causing the release of the [MINERALS] to be relatively slow. You identify the slowed "NNNNN" release as a physicochemical characteristic and state your view that the amorphous materials do not provide the primary property (fertilizer activity) for which the material is valuable.

Based on the facts as you described them, the Agency agrees with your position: if the amorphous materials merely slow the release of the fertilizer minerals from the mixture, but do not themselves provide the fertilizer function, you clearly need not file on the amorphous materials. If, however, the amorphous materials were the source of the slow release of fertilizer minerals (what you have called the NNNN soluble mineral release), then you would need to file PMN on the material.

There has been substantial concern in several States about the use of waste-derived fertilizers. Your client will want to ensure that it meets the requirements of any State in which this product is sold. Though the issue has not yet been addressed specifically by Federal agencies, I have obtained regulations issued by the State of Washington for you to consider in thinking about, in particular, your HHHH-based product. I am told that California has issued regulations, as well. You will want to ensure that you meet the requirements of any State in which your product is sold.

I hope this letter adequately responds to your request. If you have remaining questions, feel free to contact Mr. Schutz of my staff at 202-564-9262.

Sincerely,

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch
Chemical Control Division (7405)

attachments

4463

Dear Dr. TTTT:

This letter responds to your inquiry, sent to David Schutz of my staff, dated 2 January 2003. You described a product containing both [ACID a] and [BASE B]. The [ACID a] is deprotonated in solution with the [BASE B], and it is the sulfonate anion which provides the product's desired cleaning properties. These desired properties are provided by sulfonate anions in the presence of a variety of cations, [BASE B] is not specifically necessary. However, you said that it is the deprotonated anion which provides the cleaning properties, not the protonated acid. You asked whether the amine salt of [ACID a] required premanufacture notification (PMN) under Section 5 of the Toxic Substances Control Act (TSCA) or whether it could qualify for the exemption from PMN delineated at 40 CFR 720.30(h)(7). You also asked if the anion could be considered as de-protonated [ACID a], and covered by the Inventory listing for [ACID a].

I will answer your second question first: an anion is part of a salt, and the salt is a reportable substance. Your anion cannot be considered in isolation from its cation, as de-protonated [ACID a]. Consequently, unless the salt is covered by an exemption it must be reported.

The Agency issued guidance on the (h)(7) exclusion in a June 29, 1994 letter from Joseph Carra, the then Deputy Director of OPPT. This letter states that an excluded substance is one that meets the following three criteria:

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR 720.30(h)(7) and which functions as intended [those substance types are: (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic];
- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

Based on the facts as you described them, the [ACID a]-[BASE B] salt you have described must be in salt form for your firm or its customers to use it at all, the acid neither provides the primary properties nor is the substance intended for distribution. Thus a PMN must be filed even if the acid is already the subject of an Inventory listing. If, however, a salt which can provide the primary properties were the subject of an Inventory listing, and your formulation included other cations present for reasons consistent with the criteria listed above, there would be no

requirement to file PMN on the other salts which can theoretically be said to be present, and the (h)(7) exemption would be applicable.

I hope this letter adequately responds to your concern. If you have additional questions, please call David Schutz of my staff on 202 564 9262.

Sincerely,

Linda Gerber, Chief
New Chemicals Prenotice Branch
Chemical Control Division (7405M)

4516

Dr NNN
Law Offices,

Re: Prenotice Communication 4516

Dear Dr. NNN:

I have received your letter re-sent 11 April 2003. In your letter, you requested an official Agency response on the appropriateness of your contention that CERTAIN BYPRODUCTS OF MANUFACTURE, FORMERLY INCINERATED, CAN NOW BE UPGRADED FOR COMMERCIAL USE. THERE ARE TWO LEVELS OF UPGRADE, THE SECOND OF WHICH IS ACCOMPLISHED BY FURTHER REACTING THE FIRST-LEVEL UPGRADE, AND THAT THEY can be exempt from Inventory listing under 40 Code of Federal Regulations (CFR) §720.30(h)(7). XXX At this time, the value of the byproducts is great enough that they are 'upgraded' by reacting them XXX A second upgrade using XXX can further IMPROVE and this material can be used to DO THINGS WHICH CANNOT BE DONE WITH THE LOWER LEVEL UPGRADE The material produced by the second upgrading is also called BY THE SAME NAME AS THE FIRST in the trade. You assert that the material produced in the second upgrade ought to be exempt from needing separate Inventory listing (XXXXX) based on 40 CFR §720.30(h)(7). The Agency does not agree.

As you noted, a 1994 letter from Joseph Carra, the then Deputy Director of the Office of Pollution Prevention and Toxics, provides guidance on the exclusion found at 40 CFR §720.30(h)(7). This letter states that an excluded substance is one that meets the following three criteria:

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) [those substance types are: (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion

inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent, or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic] and which functions as intended.

2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,

3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

The HIGHER LEVEL UPGRADED material you have described fails criterion (3), above. REACTANT 2 is incorporated into the HIGHER LEVEL material, and this is a raw material not involved in the synthesis of the LOWER LEVEL material. The fact that the purpose of incorporation of REACTANT 2 is to make a change in the physicochemical properties of the LOWER LEVEL material does not change the fact that the HIGHER LEVEL UPGRADED material is the material intended for distribution in commerce, and that it is made with an additional synthetic step after the production of the acid number LOWER LEVEL material. As well, having determined that the HIGHER LEVEL UPGRADED is a primary reaction product, it is this material which provides the primary property, which is as you noted the ability to participate in XXXXXXXXXXXX. Consequently, it fails criterion (2), as well. I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz on 202-564-9262.

Sincerely Yours,

Linda Gerber, Chief
New Chemicals Prenotice Branch
Chemical Control Division, Mail Stop 7405

Mr. YYY
Law Offices

Re: Prenotice Communication 4516 - Follow-up

Dear Mr YYY:

This letter partially responds to your letter sent to Henry Lau, and dated 23 July 2003. In that letter, you raise several issues for Dr. Lau's attention, and in addition request that the Agency re-examine the determination, made in my April 24,

2003 letter to Dr. NNN of your firm, that certain[RESTATEMENT OF THE LETTER ABOVE]

The HIGHER LEVEL UPGRADED material you have described fails both above criteria.

In Dr. NNN's letter, he states that:

"The substances that result from the use of SECOND UPGRADE REACTANT as described in this letter are analogous to those described in an early EPA clarification of the (h)(7) exclusion. In this clarification, the EPA explains that the chemical substance formed when cotton is bleached would be excluded from reporting under the corresponding TSCA Inventory exclusion at 40 C.F.R. § 710(d)(7). The EPA rationalizes that 'bleach is intended solely to change a specific physico-chemical characteristic of the cotton, and not to make a major compositional change which alters its general character.'"

This understanding of the (h)(7)-(d)(7) exclusions can lead to problems, and we want to correct it. The cotton in this example is itself a mixture of cellulose fibers and other materials (lignins, etc). It is the other materials which provide undesirable color, and whose chemical identity is changed in bleaching. The cellulose fibers, which provide the primary properties of the cotton, do not change chemically in the bleaching process.

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz on 202-564-9262.

Sincerely Yours,

Linda Gerber, Chief
New Chemicals Prenotice Branch
Chemical Control Division, Mail Stop 7405

4831

Mr Vvv

Re: Prenotice Communication 4831

Dear Mr. Vvv:

This letter responds to your letter of 27th July, 2004, sent to Dave Schutz of my staff. In your letter, you described your client's intended manufacture of an ink product, which is a mixture of several chemical substances. You asked that the Agency confirm your opinion that a material which you describe as "substance A", and which you describe as serving as part of the vehicle component of the ink product, is exempt from premanufacture notification (PMN) otherwise required by Section 5 of the Toxic Substances Control Act (TSCA) under the exemption at 40 Code of Federal Regulations (CFR) §720.30(h)(7) as a modifier of physicochemical properties without separate commercial use. The Agency does not agree: substance A needs to be the subject of a PMN if it is to be imported into the United States as a component of your ink product.

You note that the vehicle component of the ink carries the pigment and gives it desired physicochemical properties (disperses pigment, adjusts viscosity, fixes pigment to paper, etc.) However, you also state that substance A is made outside of the ink product and added to the mixture after it is synthesized.

The Environmental Protection Agency (EPA, Agency) has issued guidance, in the form of a June 29, 1994 letter from Joseph Carra, Deputy Director of the Office of Pollution Prevention and Toxics (OPPT) on the exclusion found at 40 CFR §720.30(h)(7) (copy attached). In this clarification, the Agency states that an excluded substance is one that meets each of the following three conditions:

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7);
- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

The EPA has determined that the situation you have presented meets neither condition 2 nor condition 3: when you formulate substance A outside of the ink mixture and add it to the ink mixture, you are distributing it in commerce as that term is used in the TSCA. Therefore, the properties it provides are its primary properties (even though its properties are not the primary properties of the ink), and it is being distributed for a commercial purpose by making it and adding it to the ink mixture.

If you have further questions, please contact Dave Schutz of my staff, on 202 260 8994.

Sincerely

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch
7405 Chemical Control Division

Ms L

Re: Prenotice Communication 4998

Dear Ms L:

This letter responds to yours of 29 August 2005 sent to David Schutz of my staff. You asked whether three LVEs filed successfully by [YOUR CLIENT] Corporation of America should have been granted, and you asked that the Agency concur with your belief that the salts for which the LVEs were submitted met the conditions for exemption from premanufacture notification ("PMN") under §5 of the TSCA described at 40 Code of Federal Regulations ("CFR") §702.30(h)(3), because they were 'incidental salts.' 40 CFR 720(h)(3) does not apply to the [YOUR CLIENT] materials, it is an exclusion for materials which form on exposure to environmental factors (air, sunlight, etc.) In the remainder of this letter, we will consider whether the exclusion at 40 CFR 720.30(h)(7) can apply.

You describe [YOUR CLIENT]'s situation as follows: Your Client makes several complex formulations for use as polishing agents in the electronics industry. You state that the salts on which LVEs L-1,2,3 were filed are not significant components of the final product; they are formed incidentally; they are not manufactured for distribution in commerce as themselves; and they have no commercial value of their own. On June 29, 1994, Joseph H. Carra, the then Deputy Director of the Office of Pollution Prevention and Toxics issued a letter of clarification on another provision of the TSCA regulations, 40 CFR 720.30 (h)(7) ("the Carra letter") This letter states that an excluded substance under 40 CFR §720.30(h)(7) is one that meets the following three criteria:

the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) and which functions as intended [those substance types are: (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic];

2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,

3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has

no commercial purpose separate from the product mixture or formulation of which it is a component.

These criteria are similar to the statements you have made in describing [YOUR CLIENT]'s salts. In reviewing [YOUR CLIENT]'s original LVE applications, however, we did not determine that the subject materials met the criteria for (h)(7) exclusion. In your LVE applications, you described them as principal component chemical substances in a water-based abrasive slurry. If we are to determine, now, that the LVEs ought not have been granted, we need to know what you mean, in your current letter, by describing the materials as not 'significant' components: beyond the question of whether they are a substantial fraction of the mixtures, do they have a positive value for the function of the products? Is their synthesis intentional? Are the desired properties of the mixture provided only by the materials which have been added to the mixture, or do the synthesized salts which were the subject of the LVEs provide desired properties?

I hope this letter enables you to make an internal determination whether the LVEs for these materials ought have been granted. If, after you consider the questions identified above, you still feel that these materials could be excluded from PMN, please write us again to request that the LVEs be withdrawn and support the contention that they are not appropriately considered to be principal component chemical substances. If you need further information, feel free to contact Dave Schutz, of my staff, on 202-564-9262.

Sincerely,

Miriam Wiggins-Lewis
Chief (acting) New Chemicals Prenotice Branch
Chemical Control Division, Mail Stop 7405M

5059

XXXXX:

Thank you for your letter dated XXXX, to Dave Schutz of my staff. Your letter asked whether 40 Code of Federal Regulations ("CFR") '720.30(h)(7) or (h)(6) exempts a CCCC used to strengthen XXXXXX pellets from premanufacture notification ("PMN") under '5 of the Toxic Substances Control Act ("TSCA"). The exemption at '720.30(h)(7) is unlikely to be appropriate unless the COMPONENT SUBSTANCES OF CCCC themselves are the providers of the binding function. Even if that is true, (h)(7) can be appropriate only if the CCCC forms during manufacture of the pellets. The exemption at '720.30(h)(6) is unlikely to be appropriate unless the shape of the pellets is critical to their use. However, based on the facts in your letter, it appears that the exemption at '720.30(h)(5) would cover a binder such as you describe.

In your current practice, COMPONENT SUBSTANCES OF CCCC are added to XXXXX, extruded, and heat treated. During the heat treatment, the COMPONENT SUBSTANCES OF CCCC combine with each other and form CCCC, holding the XXXXX particles together in cylindrical pellets. Neither the CCCC nor any of its COMPONENT SUBSTANCES reacts with the XXXXX. XXXXX XXXXXXXXXXX XXXXXXXX XXXXXXXX A detailed response to your questions follows:

1. Can the XXXXX be exempted from PMN through the "incidental chemical" exemption at 40 CFR '720.30(h)(7)?

As you noted, a 1994 letter from Joseph Carra, the then Deputy Director of the Office of Pollution Prevention and Toxics, provides guidance on the exclusion found at 40 CFR '720.30(h)(7). This letter states that an excluded substance is one that meets the following three criteria:

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR '720.30(h)(7) [those substance types are: (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic];
- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

Your purpose in adding COMPONENT SUBSTANCES OF CCCC to the XXXXX appears to be as raw materials for the CCCCC. It is the CCCCC which has the intended purpose as a binder. As raw materials for the binder CCCCC, the COMPONENT SUBSTANCES OF CCCC have neither any of the specific functions nor the general "physicochemical characteristic" function named in Criterion 1. Consequently, the exemption at '720.30(h)(7) will not apply in this case.

Please note that even if you made the CCCCC outside of the pellets and added it to the XXXXX to form pellets, the exemption at '720.30(h)(7) would still not apply. Once you made the CCCCC outside of pellet extruder, the synthesis of the CCCCC and its addition to the pellets would constitute distribution in commerce of a substance whose primary property was binding, so it would fail Criteria 2 and 3.

2. Can the cylindrical shape of the pellets allow the CCCCC to be exempted from PMN through the "article" exemption at 40 CFR '720.30(h)(6)?

An article is defined in the PMN regulations as a manufactured item for which the shape or design is necessary to its function. 40 CFR 720.3(c) defines "article" as

"...a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical

composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article..."

You describe the cylindrical shape of the pellets and suggest that they should be considered to be "articles" as defined at 40 CFR '720.3(c). The "dependent in whole or in part upon its shape or design" exemption in the regulations is to exempt a specific shape or design necessary for end use function (for example, an automobile bumper must be formed to a specific shape to be able to be bolted to the frame of the automobile for which it is made, and it must bolt to the frame to serve its function). The cylindrical shape of your pellets may well be chosen for ease of manufacture, packaging, shipping, etc. At the least, to use this exemption, you need to be able to show that the function of the XXXXXX pellets could not be attained with a different shape. If you want to make such a claim, please contact us with details and we will discuss it with you.

The "end use" exemption at 40 CFR '720.30(h)(5) appears to apply in this case.

As you describe it, your binder is a chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate. Such substances are excluded from the PMN requirements at 40 CFR '720.30(h)(5).

Similarly to the (h)(7) exemption, above, if you made the CCCCC binder outside of the pellets and added it to the pellets, the (h)(5) exemption would not apply because the synthesis of the CCCCC and its addition to the pellets would constitute distribution in commerce.

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz, of our staff, on 202-260-8994.

5105

Dr [inquirer]

Re: PC-5105

Dear Dr [inquirer]:

This letter responds to your letter dated 8 August 2006 seeking an official response on the appropriateness of exclusion from the requirement for premanufacture notification (PMN) under the Toxic Substances Control Act (TSCA) for [your material] which has been treated to increase hydrophilicity under 40 Code of Federal Regulations 40 CFR §720.30(h)(7). In your letter, you state that your client, [CLIENT] has found that it can treat [your material] with [A SALT], making its surface hydrophilic.

As you describe the situation, the [your material] after treatment with the [A SALT] looks and handles similarly to the untreated material, but because hydrophilic can absorb polar impurity materials, including water, which are not removed by untreated [your material]. This has high value for some electronic industry applications.

You describe your assessment that this situation meets the requirements of the exclusion from premanufacture notice (PMN) at 40 CFR 720.30(h)(7) as follows: the material is treated only to modify the hydrophilicity of its surface, which is a physicochemical characteristic; improvement of absorption of hydrophilic impurities does not change the primary property of the [your material] material, which is absorption of impurities in general (including hydrophilic ones at a lower efficiency); and last it is not intended for separate distribution in commerce because only enough [A SALT] is added to the [your material] to treat 10-15% of the material present, and it will not be distributed separately.

The EPA has determined that, based on the situation as you have presented it, the chemical reactions forming any new substances are intended solely to enable the product to improve its absorption of hydrophilic impurities, and that these are a subset of the impurities for which the material is intended to provide removal. Thus, the reactions are to impart certain physicochemical properties to the product or product mixture rather than to produce the substance itself. In such cases, the substance is considered excluded from PMN at 40 CFR §720(h)(7).

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz, of my staff, on 202-564-9262.

Sincerely,

Miriam Wigginslewis, Chief (acting)
New Chemicals Prenotice Branch
7405M Chemical Control Division

5407

Ms [correspondent]

Re: PC-5407

Dear Ms [correspondent]:

Thank you for your letter of 10 September 2008 to David Schutz of my staff. In your letter, you asked that EPA confirm for your client your understanding that a pouch of [DESCRIPTOR] film, developed with the intent that it would dissolve when put in water, and after dissolution release contained material XXXXX would constitute an article as defined at 40 CFR 720.3(c). At 40 CFR 720.3(c) "article" is defined as a manufactured item which: 1) is formed to a specific shape or design during manufacture, 2)

has an end use function dependent in whole or in part upon its shape or design during end use, and 3) has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article. You are correct that the pouch constitutes an article by this definition.

You also wanted confirmation that, if the film pouch article is imported, chemical substances in the film which were incorporated with no commercial purpose other than to contain the [CONTAINED MATERIAL] until it is put in water (that is, no commercial purposes separate from that of the article as described at 40 CFR 720.3(c)) would not require premanufacture notification. You refer to 40 CFR §720.22(b)(1), which states that "...Any person who intends to import a new chemical substance into the United States for commercial purposes must submit a notice, unless the substance is excluded under §720.30 or unless the substance is imported as part of an article." You are correct that 40 CFR §720.22(b) excludes the substance from the §5 notice requirement, since it satisfies the definition of 'article' at §720.3(c).

You further state the applicability of the exclusions from PMN requirements at 40 CFR §720.30(h)(4), (5), and (6) for, respectively, any chemical substance which occurs: (4) incidental to storage or disposal of an article, (5) upon end use of the article, or (6) upon use of any other chemical substance formed during the manufacture of an article. You note that the purpose of the [DESCRIPTOR] based film pouch for the dispensed material is solely containment of the [CONTAINED MATERIAL] and that, once the pouch is manufactured, the chemicals contained therein undergo no further reactions with a separate commercial purpose, do not contribute to the [CONTAINED MATERIAL], are not distributed in commerce and in fact are disposed to sewer. EPA thus agrees that any chemicals generated upon end use, storage, or disposal would be exempt under 40 CFR 40 CFR §§720.30(h)(4) & (5). You also noted 40 CFR §720.30(h)(6), which excludes from PMN requirements materials "formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance". Reference to 40 CFR §720.30(h)(6) could be relevant to a material made domestically, but is not necessary in your case, given the exclusion for an imported article at §720.22(b).

It is important to note that the fact that the non-Inventory materials you have described are excluded by the regulations from premanufacture review by EPA is not itself any indication that they are benign from an environmental or health point of view. Though these materials are exempt from premanufacture review, your clients should consider how to seek assurance that contained substances are not unreasonably harmful, since they will not get this review from the Agency in a Section 5 review process.

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz, of my staff, on 202-564-9262.

Sincerely,

Greg Schweer, Chief (Acting)
New Chemicals Prenotice Branch
7405M Chemical Control Division

5505

[CORRESPONDENT], Ph. D.

Re: Prenotice Communication 5505

Dear Dr. [CORRESPONDENT]:

You've asked Dave Schutz, of my staff, to comment on unintentional formation of a non-Inventory ('new') substance in an aqueous mixture of two Inventory-listed materials. Salts and other substances may form from the interaction of the two Inventory-listed substances in the aqueous mixture, but they are neither identified nor desired, and they are not isolated. You suggested that 40 CFR 710.4 (d) (3) excludes it from Inventory and Premanufacture (PMN) notice requirements.

You are correct that substances created unintentionally in the manner you describe in your letter are exempt from TSCA PMN requirements. The best source of authority to support this proposition is 40 CFR 720.30 (h) (4) in the PMN rule. Your letter references 40 CFR 710.4 (d) (3), but Part 710 is the regulation covering the Initial Inventory and ongoing Inventory Update reporting, whereas the PMN requirements are codified at Part 720. Your chemicals may also be exempt under 40 CFR 720.30 (h) (7)

If you have any questions or comments, please contact Mr. Schutz at 202 564 9262

5656

Mr. XYYX

Re: PC 5656

Dear Mr. [XYYX]:

Thank you for your email sent 22 July 2010 to Dave Schutz, of my staff. You asked for Agency agreement that 2 cases of salts formed in a product mixture made by your client do not constitute new substances requiring premanufacture notification ("PMN") under §5 of the Toxic Substances Control Act ("TSCA").

You described your situation: your client makes product mixtures. The components of the mixtures with which you are concerned are Inventory-listed polymers, not soluble or dispersible in water. The product mixture also includes a suspension agent containing either acetic acid or ammonia and several surfactants, which functions to neutralize the functional groups on the polymers and enable a stable

and usable aqueous suspension. You are aware that the acid or amine will neutralize the polymer, forming a salt. You asked that the Agency concur with your belief that the salt met the conditions for exemption from PMN under §5 of the TSCA described at 40 Code of Federal Regulations ("CFR") §702.30(h)(7).

A 1994 letter from Joseph Carra, the then Deputy Director of the Office of Pollution Prevention and Toxics, provides guidance on the exclusion found at 40 CFR §720.30(h)(7). This letter states that an excluded substance is one that meets the following three criteria:

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) functions as intended [those substance types are: (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic];
- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

You have identified your purpose in adding the suspension agents to the mixtures as production of a 'stable and useful aqueous suspension'. You have not, however, clarified whether the polymer can be useful for its primary purpose without being transformed into a salt, nor have you explained whether the salt is made within the final mixture or outside of it. If it cannot be useful for its primary purpose without making the salt, then the salt formation fails criterion 3, above, and must be notified. Based on your description, and assuming that the polymers can serve their function whether or not transformed into salts, they appear to meet all three criteria identified above, and are appropriately exempted under §720.30(h)(7).

Please note, as well, that the suspension cannot be added into another mixture after the salt is formed: such a stock solution would constitute commercial use of the salt, so would also fail #3 above, and it would be subject to PMN.

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz, of our staff, on 202-564-9262.

Sincerely Yours,

Greg Schweer, Chief
New Chemicals Management Branch
7405 Chemical Control Division

6138

Mr.[YXYX]

Re: Prenotice Communication 6138

Dear Mr. [YXYX]:

Thank you for your facsimile sent 17 February, 2011 to Dave Schutz, of my staff. You asked for Agency agreement that salts formed in a [Your Company] product mixture do not constitute a new substances requiring premanufacture notification ("PMN") under §5 of the Toxic Substances Control Act ("TSCA").

You have explained your situation in your facsimile: you make a product mixture. The component of the mixture which provides its primary property is a rust inhibitor. The product mixture also includes [ACIDIC MATERIAL] and [BASIC AMINE] which function only to stabilize the emulsion. You are aware that the acids and amine will neutralize, forming salts. It appears from your facsimile that the acids and the amine are not mixed together before they are separately introduced into the mixture. The salt is not the source of the desired properties of the mixture. You asked that the Agency concur with your belief that the salt met the conditions for exemption from PMN under §5 of the TSCA described at 40 Code of Federal Regulations ("CFR") §702.30(h)(7).

A 1994 letter from Joseph Carra, the then Deputy Director of the Office of Pollution Prevention and Toxics, provides guidance on the exclusion found at 40 CFR §720.30(h)(7). This letter states that an excluded substance is one that meets the following three criteria:

1. the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) functions as intended [those substance types are: (i) a **stabilizer**, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic];
2. the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
3. the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

You have identified your purposes in adding the amine and the acids to the mixture, and stated that the salt is incidental to those purposes. Based on your description, the salt appears to meet all three criteria identified above, and is appropriately exempted under §720.30(h)(7).

I want to provide a caution if it is your intent that the amine and acids are to be made up into stock solutions: such stock solutions must not be solutions of the amine plus the acid (that is, of the salt) - addition of the salt which had formed in a stock solution to the rest of the mixture would constitute commercial use of the salt and it would then be subject to PMN. Only if the salt forms in the rust inhibiting coating solution does §720.30(h)(7) exclude it from PMN.

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Dave Schutz, of our staff, on 202 564 9262.

6245

ffff,

Re: Prenotice Communication 6245

Dear Ms fffff:

On 9 May, 2011, you wrote to Dave Schutz of my staff, asking whether a neutralization which is occurring in an intended new product mixture is producing a new chemical substance which would require review under the Toxic Substances Control Act (TSCA) New Chemicals program.

In your letter, you stated that your product is a corrosion inhibitor in the manufacture of which [ACIDIC AND BASIC MATERIALS] are combined in a XXXX base. You are aware that in neutralization these materials will form salts. You asked that the Agency concur with your belief that the salt met the conditions for exemption from premanufacture notice requirements under §5 of the TSCA described at 40 Code of Federal Regulations ("CFR") §720.30(h)(7).

A 1994 letter from Joseph Carra, the then Deputy Director of the Office of Pollution Prevention and Toxics, provides guidance on the exclusion found at 40 CFR §720.30(h)(7). This letter states that an excluded substance is one that meets the following three criteria:

- 1) the substance is formed from a chemical reaction that involves the use of a substance of the type described under 40 CFR §720.30(h)(7) functions as intended [those substance types are: (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic];
- 2) the substance does not function to provide the primary properties that determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and,
- 3) the substance is not itself the one intended for distribution in commerce. Although it may be a component of the product mixture or formulation actually distributed in commerce, it has no commercial purpose separate from the product mixture or formulation of which it is a component.

You have identified your purpose in making the mixture as inhibition of corrosion. You have not, however, clarified whether the substances in the mixture can be useful for their primary purpose without being transformed into salt(s), nor have you explained whether the salt is made within the final mixture or outside of it. If the materials cannot be useful for their primary purpose without making the salt, then the salt formation fails criterion 3, above, and must be notified. If the materials in the mixture can serve their function whether or not transformed into salts, they appear to meet all three criteria identified above, and are appropriately exempted under §720.30(h)(7).

Please also note, that the corrosion inhibitor formulation cannot be added into another mixture after the salt is formed: such a stock solution would constitute commercial use of the salt, so would also fail criterion #3 above, and it would be subject to PMN.

I hope this discussion adequately addresses your concerns. If you have remaining questions, feel free to contact Mr. Schutz on 202-564-9262.